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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/807,377

03/24/2004

Takashi Yoshimura

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EXAMINER

WILSON, MICHAEL C

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 05/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/807,377	Applicant(s) YOSHIMURA ET AL.	
	Examiner Michael C. Wilson	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-10 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-10 are pending. It is assumed that claims 9 and 10 should begin "The transformed animal according to claim 8" and not "The method according to claim 8...".

Specification

The description of Fig. 4 on pg 3 should include separate descriptions of both photographs in Fig. 4A and Fig. 4B.

The description of Fig. 5 on pg 3 should include separate descriptions of both graphs in Fig. 5A and Fig. 5B.

The description of Fig. 6 on pg 3 should include separate descriptions of both photographs in Fig. 6A and Fig. 6B.

The description of Fig. 7 on pg 3 should include separate descriptions of both graphs in Fig. 7A and Fig. 7B.

The description of Fig. 8 on pg 3 should include separate descriptions of the three graphs in Fig. 8A-8C.

The description of Fig. 9 on pg 3 should include separate descriptions of the three graphs in Fig. 9A-9C.

The description of Fig. 10 on pg 3 should include separate descriptions of the three graphs in Fig. 10A-10B.

Please include support for the amendments and do not include any new matter. If literal support for the amendments is not in the specification as originally filed, please describe why the amended descriptions are readily apparent from the photographs or

graphs in the Figures or from the specification as originally filed. Please begin the descriptions as Fig. 4A-4B, Fig. 5A-5B, etc.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, drawn to a method for promoting gonadal growth in a mammal by administering thyroid hormone or its derivatives to the mammal, classified in class 530, subclass 399.
- II. Claims 1-4, drawn to a method for promoting gonadal growth in a bird by administering thyroid hormone or its derivatives to the bird, classified in class 530, subclass 399.
- III. Claims 5 and 6, drawn to a method for promoting gonadal growth in a mammal by administering DNA encoding type II deiodinase to the mammal, classified in class 514, subclass 44 and class 800, subclass 21.
- IV. Claims 5-7, drawn to a method for promoting gonadal growth in a bird by administering DNA encoding type II deiodinase to the bird, classified in class 514, subclass 44 and class 800, subclass 21.
- V. Claims 8 and 9, drawn to a transformed mammal introduced with a gene encoding type II deiodinase into the mammal, classified in class 800, subclass 14.
- VI. Claim 8-10, drawn to a transformed bird introduced with a gene encoding type II deiodinase into the bird, classified in class 800, subclass 19.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the related inventions do not overlap in scope because promoting gonadal growth in mammals and birds requires different types of thyroid hormones. Thyroid hormones that function in mammals may not function in birds and vice versa. Therefore, the methods steps for promoting gonadal growth in mammals and birds are mutually exclusive.

Groups I and II are patentably distinct from Groups III and IV because Groups I and II require administering thyroid hormone such as triiodothyronine into the animal while Groups III and IV require administering DNA encoding type II deiodinase into the animal. The protocols and reagents required to promote gonadal growth in an animal using a thyroid hormone are materially distinct and separate from those required to promote gonadal growth in an animal using DNA. The burden required to search both methods together would be undue. Promoting gonadal growth in an animal using a thyroid hormone does not require administering DNA encoding type II deiodinase and vice versa.

Groups I and II are patentably distinct from Groups V and VI because Groups I and II require administering thyroid hormone such as triiodothyronine into the animal while Groups V and VI require a transformed animal "introduced with a gene encoding

type II deiodinase into the animal.” The protocols and reagents required to promote gonadal growth in an animal using a thyroid hormone are materially distinct and separate from those required to make a transformed animal using a gene encoding type II deiodinase. The burden required to search the unrelated method and product together would be undue. Promoting gonadal growth in an animal using a thyroid hormone does not require a transformed animal introduced with a gene encoding type II deiodinase and vice versa.

Inventions III and IV are directed to related processes. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the related inventions do not overlap in scope because promoting gonadal growth in mammals and birds requires different type II deiodinase genes. A type II deiodinase gene that functions in mammals may not function in birds and vice versa. Therefore, the methods steps and reagents for promoting gonadal growth in mammals and birds using a type II deiodnase gene are mutually exclusive.

Inventions III or IV and V or VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the process can be used to

make two materially distinct products: an animal treated by gene therapy or a transgenic animal. An animal treated by gene therapy has cells comprising a vector encoding an exogenous gene while a transgenic animal has a genome comprising an exogenous gene. Similarly, the "transformed animals" of Groups V and VI can be made by gene therapy or transgenesis. The processes for gene therapy and for transgenesis require materially distinct protocols and reagents. The products produced (an animal treated by gene therapy and a transgenic animal) have materially distinct structures and would require different searches. The burden required to search both the process of promoting gonadal growth in an animal with the transformed animal would be undue.

Groups V and VI are directed to related products. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the products do not overlap in scope because the structure of mammals and birds are different and the genes required to promote gonadal growth in mammals and birds are different.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

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Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on 571-272-0735.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson



**MICHAEL WILSON
PRIMARY EXAMINER**